

## **REMARKS**

Applicants acknowledge with appreciation the Office's withdrawal of the objections to the claims under the first paragraph of the Office Action mailed June 17, 2004. Applicants also acknowledge with appreciation the Office's withdrawal of the objections to and rejections of the claims asserted in the prior Office Action under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. In addition, Applicants acknowledge with appreciation the Office's withdrawal of the objections to and rejections of the claims asserted in the prior Office Action for alleged double patenting.

Claims 1-18, 21, 28-35, and 41-44 were pending. Applicants have added claim 45 to encompass a more specific ratio of the invention, *i.e.*, 5:1 to 4:1, which finds support throughout the specification, including at page 20, lines 13-16 ("Formononetin and one or more of biochanin, genistein and daidzein, are provided in a ratio of formononetin to the other isoflavones, whether alone or in combination, in a ratio of 15:1 to 2:1, preferably 10:1 to 5:1. A composition formed therefrom may then be administered to humans."), and at Example 2, page 23, lines 25-27 (for the ratio of 4:1). No new matter is added. With the entry of this amendment, claims 1-18, 21, 28-34, and 41-45 are currently pending.

### **Claim Rejections Under 35 U.S.C. § 103**

The Office has maintained the rejection of all the claims under 35 U.S.C. § 103(a) as unpatentable over Kelly WO 93/23069 ("Kelly '069") in view of Empie et al., U.S. Patent No. 6,261,565 B1 ("Empie") and Kelly 6,340,703 ("Kelly '703"), asserting that Applicants' prior declarations did not remove Kelly '703 as prior art.

In maintaining that Kelly '703 is prior art under M.P.E.P. sections 715.01(a) and 716.10, the Office states:

Regarding the 132 declarations, the MPEP states, “when subject matter, **disclosed but not claimed** in a patent or application publication filed jointly by S and another, is claimed in a later application filed by S, the joint patent or application publication is a valid reference >under 35 U.S.C. 102(a) or (e)< unless overcome by affidavit or declaration under 37 C.F.R. 1.131 or an unequivocal declaration under 37 CFR 1.132 by S that he/she conceived or invented the subject matter disclosed in the patent or application publication and relied on in the rejection. In re DeBaun, 687 F.2d 459, 213 USPQ 933 (CCPA 1982). .... Therefore, these declarations are ineffective to remove the Kelly patent 6,340,703 as prior art because the subject matter disclosed in the patent is also claimed.

Office Action at page 3.

The Office also discusses Applicants’ substantive arguments addressed to the previous claim rejection under 35 U.S.C. § 103(a), stating that Applicants’ arguments “have been considered but are not found to be persuasive.” Office Action at page 4. The Office maintains its obviousness objection and rejection, stating, “Concerning the claimed ratios having a high proportion of formononetin as well as new claim 44, the Kelly patent discloses a method of treating osteoporosis in a patient by administering to the patient a composition containing an effective amount of (10:1 to 1:10) of formononetin and daidzein (please see claims 6, 9, 14, 15).”

The Office concludes:

[S]ince Kelly ‘069 and ‘703, in particular, as well as Empie et al. have established that the therapeutic efficacy of the isoflavones is dependent upon their ratio amounts, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the methods and compositions of the prior art such that formononetin and biochanin or genistein or daidzein are present in a ratio that is effective to optimize their therapeutic activity.

Office Action at page 4. Applicants respectfully traverse.

The Office cites M.P.E.P. § 715.01(a), M.P.E.P. § 716.10 and *In re DeBaun* for the proposition that Rule 132 declarations can only be submitted where the subject matter is “disclosed but not claimed” in the pending application. Office Action at page 3. Applicants

respectfully contend that the cited M.P.E.P. sections are incorrect. While Rule 132 did previously contain language that limited its use to subject matter “disclosed but not claimed,” that language was expressly dropped in the amendments made on September 20, 2000. 65 Fed. Reg. 57,024 (Sept. 20, 2000) (Submitted as Exhibit A). In pertinent part, the Federal Register states:

Section 1.132: Section 1.132 is revised to provide that when any claim of an application or a patent under reexamination is rejected or objected to, any evidence submitted to traverse the rejection or objection on a basis not otherwise provided for must be by way of an oath or declaration under this section. This adopts the long-standing policy that any oath or declaration not otherwise provided for is considered under § 1.132. See MPEP 716.

Section 1.132 as adopted does *not* provide that an oath or declaration may *not* be submitted under § 1.132 to traverse a rejection if the rejection is based upon a U.S. patent or a U.S. patent application publication of a pending or patented application to another or others which *claims the same patentable invention* as defined in § 1.601(n). If an oath or declaration is submitted under § 1.132 to traverse a rejection, and the rejection is based upon a U.S. patent or a U.S. patent application publication of a pending or patented application to another or others which *claims the same patentable invention* as defined in § 1.601(n), the Office will consider on a case-by-case basis whether the oath or declaration may be considered sufficient to overcome the rejection, or whether the applicant will be required to establish priority of invention through an interference proceeding.

65 Fed. Reg. 57,024, 57,033 (Sept. 20, 2000) (emphasis supplied).

Section 1.132 was ultimately revised to read as follows:

§ 1.132 -- Affidavits or declarations traversing rejections or objections.

When any claim of an application or a patent under reexamination is rejected or objected to, any evidence submitted to traverse the rejection or objection on a basis not otherwise provided for must be by way of an oath or declaration under this section.

65 Fed. Reg. 57,024, 57,057 (Sept. 20, 2000).

While Section 1.132 was expressly amended in September 2000, it does not appear that M.P.E.P. Section 715.01(a) was ever amended to reflect the changes in Section 1.132. The first

sentence of Section 715.01(a), in particular, reflects the language from the old version of Section 1.132, stating there are limitations on when a Rule 132 declaration can be used to overcome a rejection. M.P.E.P. § 715.01(a) at 700-243 (“When subject matter, disclosed but not claimed in a patent or application publication....”). However, it is clear that, based on the September 2000 amendment, and regardless of the incorrect, limiting language of Section 715.01(a), a Rule 132 declaration is entirely appropriate to address subject matter that is claimed in a patent or in an application. 65 Fed. Reg. 54,604, 54,640 (Sept. 8, 2000) (Submitted as Appendix B). Indeed, the only limitation on submitting a Rule 132 declaration to overcome a prior art rejection is that the prior art not be the invention of another. *Id.*

Accordingly, Applicants respectfully suggest that the M.P.E.P. section upon which the Office relies is outdated and incorrect. Under Section 1.132, as amended, Applicants submitted proper declarations that effectively removed Kelly ‘703 as prior art.

For these reasons, Applicants request the withdrawal of the maintained rejection under Section 103.

### CONCLUSION

With the entry of this Amendment, claims 1-18, 21, 28-35, and 41-45 are pending. Applicants earnestly and respectfully request the Office to reconsider its assertion of *prima facie* obviousness and to allow the pending amended claims. Should this paper not result in a Notice of Allowance, Applicants respectfully request that the Examiner contact the undersigned at 650-849-6607 to arrange for an interview.

If there is any fee due in connection with the filing of this Amendment, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

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By: Jean B. Fordis  
Jean B. Fordis  
Reg. No. 32,984  
Customer No. 22,852